

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Currently Amended) A method of enumerating the number of CD4+ ~~(CD4-positive) lymphocytes cells or subset thereof~~ in a cell sample, the method comprising the steps of:

a) identifying the total white blood cell ~~CD45-expressing~~ population as a reference population from which the ~~for measuring~~ CD4+ lymphocytes are subsequently measured;

b) determining the percentage of CD4+ lymphocytes ~~or subset thereof~~ as a function of the total white blood cell ~~CD-45~~ reference population in a sample identified in step (a);

c) determining the number of white blood ~~CD-45~~ cells per volume of blood in the sample; and

d) calculating the absolute number of CD4+ lymphocytes ~~cells or subset thereof~~ in the sample by multiplying the percentage of CD4+ lymphocytes ~~cells or subset thereof~~, obtained in step (b), by the white cell ~~CD-45~~ count obtained in step (c).

2. (Currently Amended) A method according to claim 1, wherein the number of white blood ~~CD-45~~ cells per volume of blood is determined in step (c) by either a single platform determination of total CD45+ expressing cells, ~~method in which known numbers of beads are added to the sample and the beads and cells are counted simultaneously to obtain the absolute cell count, or by a dual platform method using a white blood cell count obtained from a haematology analyzer.~~

3. (Withdrawn) A method according to claim 1, wherein a white blood cell differential is further identified from the total CD45 expressing population identified in step (a) of claim 1, and further comprising the steps of:

- e) (i) determining the percentage of CD4 monocytes as a function of the total CD45 expressing population identified in step (a); and
 - (ii) calculating the number of CD4 monocytes in the sample by multiplying the percentage of CD4 monocytes determined in step (e(i)) by the number of CD45 cells obtained in step (c);
- f) (i) determining the percentage of CD4 eosinophils as a function of the total CD45 expressing population identified in step (a); and
 - (ii) calculating the number of CD4 eosinophils in the sample by multiplying the percentage of CD4 eosinophils determined in step (f(i)) by the number of CD45 cells obtained in step (c);
- g) (i) determining the percentage of CD4 negative granulocytes as a function of the total CD45 expressing population identified in step (a); and
 - (ii) calculating the number of CD4 negative granulocytes in the sample by multiplying the percentage of CD4 negative granulocytes determined in step (g(i)) by the number of CD45 cells obtained in step (c);
- h) (i) determining the percentage of CD4 negative lymphocytes as a function of the total CD45 expressing population identified in step (a); and
 - (ii) calculating the number of CD4 negative lymphocytes in the sample by multiplying the percentage of CD4 negative lymphocytes determined in step (h(i)) by the number of CD45 cells obtained in step (c);
- i) (i) adding the percentage of CD4 lymphocytes identified in step (b) and the percentage of CD4 negative lymphocytes obtained in step (h(i)) to obtain the percentage of total lymphocytes;

- (ii) determining the percentage of total lymphocytes as a function of the total CD45 expressing population identified in step (a); and
- (iii) calculating the number of total lymphocytes in the sample by multiplying the percentage of total lymphocytes obtained in step (i(ii)) by the number of CD45 cells obtained in step (a).

4. (Withdrawn) A method according to claim 1, further comprising the steps of:

- e) determining the percentage of basophils as a function of the total CD45 expressing population identified in step (a); and
- f) calculating the number of basophils in the sample by multiplying the percentage of basophils determined in step (j) by the number of CD45 cells obtained in step (c).

5. (Previously Presented) A method according to claim 1, wherein the sample is whole unlysed blood, unfractionated, fractionated or lysed whole blood.

6. (Withdrawn) A kit including CD4 and CD45 antibodies for use in enumerating the number of CD4 cells in a sample.

7. (Withdrawn) A kit according to claim 6, which further includes instructions for performing the method of enumerating the number of CD 4 cells in a cell sample.

8. (Withdrawn) A kit according to claim 6, which further includes one or more reagents selected from the group consisting of a red cell lysating agent, a stabilizer, a fixative, control cells, media and bead reagents.

9. (Withdrawn) A machine readable medium comprising instructions, which when executed by a machine, cause the machine to perform the method steps of claim 1.

10. (Withdrawn) A machine readable medium according to claim 9, which is configured for use in conjunction with a flow cytometer and/or haematology analyser.

11. (Withdrawn) A machine readable medium according to claim 9, which includes instructions for performing analysis methods selected from the group consisting of impedance, light scatter, fluorescence and precision volume counting.

12. (Withdrawn) The method of claim 1, wherein the method includes the step of enumerating the number of CD4+ lymphocytes or CD4+ T-cells in a cell sample from the patient with HIV or other immune deficiency condition or disease; and wherein the method is used to monitor the immune status of the patient.

13. (Withdrawn) A method according to claim 12, wherein the patient's immune status is determined or monitored to determine the patient's response to antiretroviral treatment.

14. (New) A method according to claim 2, wherein the single platform determination is performed by adding known numbers of beads to the sample and counting the beads and cells simultaneously to obtain the absolute cell count.

15. (New) A method according to claim 1, wherein the number of white blood cells per volume of blood is determined in step (c) by a dual platform determination using a haematology analyzer-derived total white blood cell count.

16. (New) A method according to claim 1, wherein the number of white blood cells per volume of blood is determined in step (c) by determination of total CD45+ expressing cells.